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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0214; FRL-9933-35]

Tetraethylene Glycol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of tetraethylene glycol (CAS Reg. No. 112-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops. Exponent, Inc. on behalf of Drexel Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of tetraethylene glycol.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0214, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0214 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0214, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10753) by Exponent, Inc. (1150 Connecticut Ave., Suite 1100 NW Washington, DC 20036) on behalf of Drexel Chemical Company, P.O. Box 13327 Memphis, TN 38113-0327. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the

requirement of a tolerance for residues of tetraethylene glycol (CAS Reg. No. 112-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops. That document referenced a summary of the petition prepared by Exponent on behalf of Drexel Chemical Company, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no substantive comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human

health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tetraethylene glycol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with tetraethylene glycol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by tetraethylene glycol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Acute, subchronic and mutagenicity studies were available but chronic, developmental, reproduction and metabolism studies were not available on tetraethylene glycol. Ethylene glycol and the higher glycols (di-, tri-, tetra-, and pentaethylene glycol) are closely related in structure. Their physicochemical properties differ in a regular and expected way due to the increasing molecular weight and consistent functionality of a relatively less stable hydroxy moiety on each end of the molecule. Therefore, the hazard profile and dose response are also expected to change consistently with decreasing potential for adverse effect with increasing molecular weight (OECD SIDS SIAM 18, 2004). Based on this, toxicity data on triethylene glycol (which has a lower molecular weight than tetraethylene glycol and is likely to provide a conservative estimate of potential for adverse effect) was used as surrogate data to bridge chronic, developmental, reproduction toxicity and metabolism data for tetraethylene glycol.

The acute oral and dermal toxicity of tetraethylene glycol is low. The oral and dermal LD₅₀s are > 20,000 mg/kg (milligram/kilogram) in the rat and rabbit. Acute inhalation toxicity in rats is also low; the LC₅₀ is > 2.5 liter (L)/min. Tetraethylene glycol is mildly irritating to the eyes and to the skin in rabbits. It is not a dermal sensitizer.

Tetraethylene glycol did not cause toxicity at doses up to 2,000 milligrams/kilograms/day (mg/kg/day) in a subchronic oral toxicity study in rats.

Based on developmental and reproduction toxicity studies with triethylene glycol, tetraethylene glycol is not expected to be a developmental/reproduction toxicant. Neither maternal, developmental nor reproduction toxicity was observed up to 3,300 mg/kg/day (greater than three times the limit dose).

Available mutagenicity studies included the Ames test, mammalian gene mutation, sister chromatid exchange, chromosome aberrations, the chromatid dominant lethal test, and mouse micronucleus assays. Tetraethylene glycol was negative for inducing mutations and aberrations in all of the studies except the sister chromatid exchange assay which was positive. However, based on the weight of evidence tetraethylene glycol is not expected to be mutagenic.

Carcinogenicity studies were not available. However, based on the lack of systemic toxicity and the lack of mutagenicity tetraethylene glycol is not expected to be carcinogenic.

Neurotoxicity and immunotoxicity studies were not available for review. However, evidence of neurotoxicity and immunotoxicity was not observed in the available studies.

Metabolism studies are not available on tetraethylene glycol. However, it is postulated that the metabolic pathway for tetraethylene glycol is similar to that of triethylene glycol in that it undergoes oxidation via alcohol dehydrogenases and aldehyde dehydrogenases to generate dicarboxylic acid metabolites.

Specific information on the studies received and the nature of the adverse effects caused by tetraethylene glycol as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in the document, "Tetraethylene Glycol; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2015-0214.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that tetraethylene glycol has low toxicity. No effects were observed up to 2,000 mg/kg/day following subchronic exposure. In the developmental and reproduction toxicity studies, effects were observed only at very high doses (\geq 3,300 mg/kg/day). Further, the only effect observed at 3,300 mg/kg/day was a minor decrement in bodyweight. Although, doses between 590 - 3300 mg/kg/day were not tested in the developmental and reproduction studies in mice, the Agency is reasonably certain that no harm will occur to the general population or infants and children following the use of tetraethylene glycol at any dose below the limit dose given the lack of effects being found and the fact that the only effect seen was a minor bodyweight decrease seen at 3,300 mg/kg/day. Since, no other effects were observed, the Agency concluded that there are no endpoints of concern for tetraethylene glycol and a qualitative risk assessment is appropriate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tetraethylene glycol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from tetraethylene glycol in food as follows:

Tetraethylene glycol will be used as a solvent in pesticide formulations used on agricultural crops. Additionally, it is used as an indirect food additive.

For the general population, the majority of exposure to tetraethylene glycol occurs from the extensive use as a FDA-approved indirect food additive. Under this exemption from the requirement of a tolerance, residues of this chemical also may be found on treated crops. Because no hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Tetraethylene glycol is used as an inert ingredient in non-food use pesticide formulations and is also used as a humectant in cosmetics. However, based on the lack of toxicity, a quantitative exposure assessment from residential exposures was not performed.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found tetraethylene glycol to share a common mechanism of toxicity with any other substances, and tetraethylene glycol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tetraethylene glycol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of tetraethylene glycol and its chemical properties, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of tetraethylene glycol will not pose a risk to the U.S.

population, including infants and children, and that no harm will result to the general population, or to infants and children from aggregate exposure to tetraethylene glycol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of tetraethylene glycol in or on any food commodities. EPA is establishing a limitation on the amount of tetraethylene glycol that may be used in pesticide formulations applied to growing crops. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops for sale or distribution that contains of tetraethylene glycol.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for tetraethylene glycol (CAS Reg. No. 112-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 3, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, add alphabetically the inert ingredient “Tetraethylene glycol” to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses

Tetraethylene glycol (CAS Reg. No. 112-60-7)		Solvent
